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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888**

**[Docket No. 99N–0035]**

# Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing to reclassify 38 preamendments class III devices into class II (special controls). FDA is also identifying the proposed special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. This reclassification is being proposed on the agency's own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (the SMDA) and the FDA Modernization Act of 1997 (FDAMA). The agency is also proposing that the identification of six of the devices subject to this proposal be modified to more accurately reflect the characteristics of devices actually being marketed.

**DATES:** Written comments by (*insert date 90 days after date of publication in the* **Federal Register**). See section X of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** Submit written comments to the Documents Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301–594–1184.

**SUPPLEMENTARY INFORMATION:**

## I. Regulatory Authorities

The act, as amended by the 1976 Medical Device Amendments (the amendments) (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 105–115), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendment devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval, or reclassifies the device under 513(f). The agency determines whether new devices are substantially equivalent to previously offered devices by means

of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification (510(k)) procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

The SMDA added section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to issue an order to manufacturers of preamendment class III devices and substantially equivalent postamendments devices for which no final regulation requiring the submission of PMA's has been issued. This order requires such manufacturers to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information that has not been submitted under section 519 of the act (21 U.S.C. 360i), which requires manufacturers, importers, distributors, and device user facilities to submit adverse event reports of certain device-related events and reports of certain corrective actions taken. Section 515(i) of the act (21 U.S.C. 360e) also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III and establish a schedule for the issuance of a rule requiring the submission of PMA's for those devices remaining in class III.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced the availability of a document setting forth its strategy for implementing section 515(i) of the act. Under this plan, the agency divided preamendment class III devices into the following three groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are in very limited use; Group 2 devices are devices that FDA believes have a high potential for being reclassified; and Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA also announced its intention to call for submission of PMA's for the 15 highest priority devices

in Group 3, and for all Group 1 devices. The agency also announced its intention to issue an order under section 515(i) of the act for the remaining Group 3 devices and for all Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 41986), FDA published two orders for certain class III devices, requiring the submission of safety and effectiveness information in accordance with the preamendments class III strategy for implementing section 515(i) of the act. FDA published two updated orders in the **Federal Register** of June 13, 1997 (62 FR 32352 and 32355). The orders described in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would clearly support reclassification or indicate that a device should be retained in class III. The orders also scheduled the required submissions in groups, at 6-month intervals, beginning on August 14, 1996.

Reclassification of classified preamendments devices is governed by section 513(e) of the act (21 U.S.C. 360c(e)). This section provides that FDA may, by rulemaking, reclassify a device based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act (21 U.S.C. 360c(e)), includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in ''medical science.,'' (see *Upjohn* v. *Finch*, supra, 422 F.2d at 951), or in light of newly available regulatory controls (cf. *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 388–389 (D.D.C. 1991)), such as special controls or design controls. However, regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3)) and § 860.7(c)(2) (21

CFR 860.7(c)(2)). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices.

## II. Regulatory History of the Devices

The 38 devices subject to this proposal were classified by final rules published in the **Federal Register** in parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888 (21 CFR parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888). In the proposed rules upon which the final rules were based, FDA considered the recommendations of the device classification advisory panels regarding the classification of preamendments medical devices. Subsequently, FDA classified the devices subject to this proposal into class III, because there was insufficient information to determine that class I or class II controls could provide reasonable assurance of the safety and effectiveness of these devices. The **Federal Register** citations and publication dates for the proposed and final rules classifying the devices subject to this proposal are provided in Table 1. as follows:

TABLE 1.—PUBLICATION DATES FOR THE PROPOSAL AND FINAL RULES CLASSIFYING THE DEVICES SUBJECT TO THIS PROPOSAL

| 21 CFR Part and Device | Proposed Rule | Final Rule |
|---|---|---|
| Part 864, Hematology/Pathology | September 11, 1979, 44 FR 52950 | September 12, 1980, 45 FR 60576 |
| Part 866, Immunology/Microbiology | April 22, 1980, 45 FR 27204 | November 9, 1982, 47 FR 50283 |
| Part 868, Anesthesiology | November 2, 1979, 44 FR 63292 | July 16, 1982, 47 FR 31130 |
| Part 870, Cardiovascular | March 9, 1979, 44 FR 13284 | February 5, 1980, 45 FR 7904 |
| Part 872, Dental | December 30, 1980, 45 FR 85962 | August 12, 1987, 52 FR 30082 |
| Part 874, Ear, Nose, and Throat | January 22, 1982, 47 FR 3280 | November 6, 1986, 51 FR 40389 |
| Part 876, Gastroenterology/Urology | January 23, 1981, 46 FR 7562 | November 23, 1983, 48 FR 53012 |
| Part 878, General and Plastic Surgery | January 19, 1982, 47 FR 2810 | June 24, 1988, 53 FR 23856 |
| Part 884, Obstetrical and Gynecological | April 3, 1979, 44 FR 19894 | February 26, 1980, 45 FR 12682 |
| Part 886, Ophthalmic | January 26, 1982, 47 FR 3694 | September 2, 1987, 52 FR 33346 |
| Part 888, Orthopedic | July 2, 1982, 47 FR 29052 | September 4, 1987, 52 FR 33686 |

In accordance with section 513(e) of the act and § 860.130 (21 CFR 860.130), based upon new information received or otherwise available to the agency with respect to the devices subject to this proposal, FDA, on its own initiative, is proposing to reclassify 38 preamendments class III devices to class II. Consistent with the act and the regulation, FDA did not refer the proposed reclassifications to the panels for their recommendations on the requested change in classifications.

## III. Proposed Changes to Device Names and Identifications

Since initial classification of the 38 devices subject to this proposal, there have been many advances in the medical device industry. These advances have led to many changes, including the use of alternative materials, and/or modifications of the intended uses for some devices. Because the changes have been of sufficiently low impact on safety and effectiveness, FDA determined that the modified devices were substantially equivalent to the respective predicate devices. In some cases, however, the substantially equivalent device differs slightly from the device description found in the agency's regulations. In order to more accurately reflect the characteristics of the actual marketed devices subject to this proposal, the agency is proposing certain technical amendments be made to six device identifications, as listed in section III of this document. The agency stresses that these amendments are not intended to impose any additional restrictions on the marketed devices; rather, they are intended to accurately reflect the characteristics of marketed devices. The following changes in device identifications are being proposed.

### *A. Section 876.5860—High Permeability Hemodialysis System*

A high permeability hemodialysis system is a device intended for use as an artificial kidney system for the treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, and hemoconcentration. Using a hemodialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional hemodialysis system described in § 876.5820, the high permeability hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood from the patient is circulated through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and monitors the parameters related to this processing, including the rate at which blood and dialysate

are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices:

(1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient (Kuf) greater than 12 milliliters per hour per millimeters of mercury (mL/h/mmHg), and is used with either an automated ultrafiltration controller or another method of ultrafiltration control to prevent fluid imbalance.

(2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.).

(3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).

*B. Section 878.3610—Esophageal Prosthesis*

An esophageal prosthesis is a rigid, flexible, or expandable tubular device constructed of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

*C. Section 878.3720—Tracheal Prosthesis*

A tracheal prosthesis is a rigid, flexible, or expandable tubular device constructed of a silicone, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the trachea or tracheal-bronchial tree. It may be unbranched or contain one or two branches. The metal tracheal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

*D. Section 886.3400—Keratoprosthesis*

A keratoprosthesis is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye which is not a reasonable candidate for a corneal transplant.

This identification recognizes the temporary use of the device intraoperatively, and removes the description of the device as being made of only plastic material.

*E. Section 886.3920—Aqueous Shunt (previously ''Eye valve implant'')*

An aqueous shunt is a one-way, pressure sensitive device intended to be implanted to normalize intraocular pressure. The device is intended to treat neurovascular glaucoma or glaucomas where medical and conventional surgical treatment have failed

The agency is proposing that the name of this device be ''aqueous shunt'' rather than ''eye valve implant,'' because certain marketed devices, which have been determined to be substantially equivalent to the eye valve implant, do not contain a valve or a valve-like component.

The agency is also proposing to modify the identification of this device to more accurately reflect the device's actual use. Because the identified use of ''treatment of glaucoma'' is unnecessarily broad, the agency proposes that the identification state that the device may be used for the treatment of neovascular glaucoma or glaucomas where medical and conventional surgical treatment have failed.

*F. Section 888.3150—Elbow Joint Metal/Polymer Constrained Cemented Prosthesis*

An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted made of alloys such as cobalt-chromium-molybdenum and of an ultra-high molecular weight polyethylene bushing, and used to replace an elbow joint. The device presents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

The agency is proposing that the name and identification of the elbow joint metal/metal or metal/polymer constrained cemented prosthesis be modified to remove reference to the metal/metal prosthesis, because no metal/metal constrained cemented elbow prosthesis has ever been marketed.

## IV. Proposed Reclassification

FDA is proposing that the devices subject to this proposal be reclassified from class III to class II. FDA believes that the identified special controls would provide reasonable assurance of safety and effectiveness. Therefore, in accordance with sections 513(e) and 515(i) of the act and § 860.130, based on new information with respect to the devices, FDA, on its own initiative, is proposing to reclassify these 38 preamendments class III devices into class II. The agency has identified special controls that would provide reasonable assurance of their safety and effectiveness. The agency does not intend to exempt these proposed class II devices from premarket notification (510(k)) submissions as provided for under section 510(m) of the act (21 U.S.C. 360(m)).

## V. Proposed Special Controls.

Because several of the special controls identified in this proposal apply to 2 or more of the 38 devices addressed by this proposal, the agency has determined that it would be inefficient and redundant to individually identify, for each device, shared risks to health and corresponding special controls to address the risks to health. Instead, this document focuses on the special controls, explains the types of risks to health addressed by the special controls, and identifies the devices to which the special controls apply. For ease of review, Table 1 is included in section VI of this document following the discussion of special controls. The summary table identifies each device by name and Code of Federal Regulations (CFR) citation section number, the citation for the final rule which classified the preamendments device into Class III, and the proposed special controls applicable to the device. The special controls identified in this proposal are of four general types: FDA guidance documents, consensus standards, device specific labeling, and design and performance testing.

*A. FDA Guidance Documents*

Based on its premarket and postmarket experience and the published literature, the agency has developed the guidance documents in section V.A of this document that are designed to inform manufacturers of how the agency evaluates the safety and effectiveness of devices and reaches determinations of substantial equivalence. The guidance documents are also intended for use by FDA reviewers to ensure consistency of premarket reviews. Some FDA guidance documents are generic guidances applicable to many different devices, while others are applicable to a few related devices, or a specific device. The generic guidance documents may be referenced, and thereby incorporated into, other guidances.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). When FDA issues a final rule based on this proposal, all of the guidance documents identified as special controls will have been issued in accordance with GGP's.

Persons interested in obtaining a copy of a guidance may do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available from the Division of Small Manufacturers' Assistance (HFZ–220), Food and Drug Administration, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850.

FDA guidances are periodically updated as new information becomes available. When an FDA guidance that has been identified as a special control is revised, a notice of availability of the revised guidance will be published in the **Federal Register**, as well as a proposal to amend the special control(s) for the relevant device(s) to include the revised guidance. The following is a list and description of guidance documents that FDA proposes to use as special controls:

1. Use of International Standard ISO 10993, ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing'' (biocompatibility guidance)

During the classification of the preamendments devices, the device classification panels (the panels) identified potential adverse tissue reactions as a risk to health common to devices that contact the body. These adverse tissue reactions were identified generally, or more specifically according to the type of tissue reaction (e.g., sensitization, pyrogen reaction, hemolysis, etc.). The agency believes that the information contained in this biocompatibility guidance is adequate to control the risks to health related to adverse tissue reaction.

Therefore, the agency is proposing that the biocompability guidance be a special control applied to the following 27 devices: Indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer (§ 868.1150), indwelling blood hydrogen ion concentration (pH) analyzer (§ 868.1170), indwelling blood oxygen partial pressure ($P_{O2}$) analyzer (§ 868.1200), cardiovascular intravascular filter (§ 870.3375), vascular graft prosthesis of less than 6-millimeters diameter (§ 870.3450), pacemaker lead adaptor (§ 870.3620), annuloplasty ring (§ 870.3800), cardiopulmonary bypass defoamer (§ 870.4230), cardiopulmonary bypass arterial line blood filter (§ 870.4260), cardiopulmonary bypass oxygenator (§ 870.4350), OTC (over-the-counter) denture cushion or pad (§ 872.3540), OTC denture reliner (§ 872.3560), OTC denture repair kit (§ 872.3570), partially fabricated denture kit (§ 872.3600), high permeability hemodialysis system (§ 876.5860), peritoneo-venous shunt (§ 876.5955), endometrial aspirator (§ 884.1060), endometrial brush (§ 884.1100), endometrial washer (§ 884.1185), endoscopic electrocautery and accessories (§ 884.4100), bipolar endoscopic coagulator-cutter and accessories (§ 884.4150), keratoprosthesis (§ 886.3400), aqueous shunt (§ 886.3920), elbow joint metal/polymer constrained cemented prosthesis (§ 888.3150), knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540), shoulder joint metal/polymer nonconstrained cemented prosthesis (§ 888.3650), and shoulder joint metal/ polymer semi-constrained cemented prosthesis (§ 888.3660).

2. ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1 (Sterility Guidance)''

During the classification of the preamendments devices, the panels identified potential infection as a risk to health common to the use of many devices. The potential risk of infection would be minimized if the device were properly sterilized prior to use and appropriately labeled. Since classification of the devices subject to this proposal, the agency has developed the sterility guidance. It provides information about the use and application of national and international sterility consensus standards for devices to be labeled as ''sterile.'' The agency believes that the information contained in this guidance document is adequate to control for the potential risks to health related to infection.

Therefore, the agency is proposing that the sterility guidance be a special control for the following 23 devices: Indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer (§ 868.1150), indwelling blood hydrogen ion concentration (pH) analyzer (§ 868.1170), indwelling blood oxygen partial pressure ($P_{O2}$) analyzer (§ 868.1200), cardiovascular intravascular filter (§ 870.3375), vascular graft prosthesis of less than 6-millimeters diameter (§ 870.3450), pacemaker lead adaptor (§ 870.3620), annuloplasty ring (§ 870.3800), cardiopulmonary bypass defoamer (§ 870.4230), cardiopulmonary bypass arterial line blood filter (§ 870.4260), cardiopulmonary bypass oxygenator (§ 870.4350), electrohydraulic lithotriptor (§ 876.4480), peritoneo-venous shunt (§ 876.5955), endometrial aspirator (§ 884.1060), endometrial brush (§ 884.1100), endometrial washer (§ 884.1185), endoscopic electrocautery and accessories (§ 884.4100), bipolar endoscopic coagulator-cutter and accessories (§ 884.4150), keratoprosthesis (§ 886.3400), eye valve implant (§ 886.3920), elbow joint metal/polymer constrained cemented prosthesis (§ 888.3150), knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540), shoulder joint metal/polymer nonconstrained cemented prosthesis (§ 888.3650), and shoulder joint metal/polymer semi-constrained cemented prosthesis (§ 888.3660).

3. ''Guidance Document for the Submission of Erythropoietin Assay Premarket Notification (510(k))''

During the classification of the preamendments devices, the Hematology and Pathology Devices Classification Panel identified as risks to health, complications associated with misdiagnosis of a disease state. Since classification of this device, the agency has developed a guidance document describing its present conclusions regarding the materials, labeling, and testing controls for erythropoietin assay devices. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Guidance Document for the Submission of Erythropoietin Assay Premarket Notification (510(k))'' be a special control for the erythropoietin assay (§ 864.7250).

4. ''Guidance Document for the Submission of Fibrin Monomer Paracoagulation Test Premarket Notification (510(k))''

During the classification of the preamendments devices, the Hematology and Pathology Devices Classification Panel identified as risks to health associated with the use of this device, complications associated with misdiagnosis of a disease state. Since classification of this device, the agency has developed a guidance document describing its present conclusions regarding the materials, labeling, and testing controls for fibrin monomer paracoagulation test devices. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Guidance Document for the Submission of Fibrin Monomer Paracoagulation Test Premarket Notifications (510(k))'' be a special control for the fibrin monomer paracoagulation test (§ 864.7300).

5. ''Reviewer Guidance for Clinical Studies and Labeling for Indwelling Blood Gas Analyzers''

During the classification of the preamendments devices, the Anesthesiology and Respiratory Therapy Device Classification Panel identified as a risk to health common to indwelling blood gas analyzers, the potential for inaccurate measurement which would lead to inappropriate therapy. Since their classification, the agency has developed a guidance document describing its present conclusions regarding the appropriate clinical testing to ensure that indwelling blood gas analyzers function properly, and labeling which would ensure that the devices would be used properly, thus

minimizing the risk of inaccurate measurement of blood gasses. Because the agency believes that the information contained in this guidance document, in combination with the guidances described below, is adequate to address the risks to health, the agency is proposing that the ''Reviewer Guidance for Clinical Studies and Labeling for Indwelling Blood Gas Analyzers'' be a special control for the following three devices: Indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer (§ 868.1150), indwelling blood hydrogen ion concentration (pH) analyzer (§ 868.1170), and indwelling blood oxygen partial pressure ($P_{O2}$) analyzer (§ 868.1200).

To further minimize the risk of inaccurate measurement by indwelling blood gas analyzers, the agency is proposing that the ''Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review and the Reviewer Guidance for Format and Content of Premarket Notifications (510(k) Submissions), Labeling, Performance and Environmental Testing for Electronic Devices'' be special controls for the following three devices: Indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer (§ 868.1150), indwelling blood hydrogen ion concentration (pH) analyzer (§ 868.1170), and indwelling blood oxygen partial pressure ($P_{O2}$) analyzer (§ 868.1200). These guidance documents provide more details about the agency's present conclusions regarding testing, labeling, and manufacturing information which would be required for premarket notifications (510(k)) for these device. The agency believes that these guidance documents are adequate to address the identified risk to health.

6. ''Guidance Document for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters''

During the classification of the preamendments devices, the Circulatory System Devices Classification Panel identified as risks to health the following potential complications associated with the use of the cardiovascular intravascular filter: Pulmonary thromboembolism when anticoagulants are contraindicated, failure of anticoagulant therapy in thromboembolic diseases, chronic recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated. Since classification of this device, the agency has developed a guidance document describing its

present conclusions regarding the labeling, biocompatibility testing, mechanical testing, sterilization procedures and labeling, and clinical data controls that would ensure the safety and effectiveness of cardiovascular intravascular filters seeking 510(k) clearance. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Guidance Document for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters'' be a special control for the cardiovascular intravascular filter (§ 870.3375).

7. ''Document for Special Controls for Vascular Prostheses''

During the classification of the preamendments devices, the Circulatory System Devices Classification Panel identified as risks to health associated with the use of the vascular prosthesis, the potentials for: Thrombosis, embolism, occlusion stenosis, leakage, graft disruption, seroma, pseudoaneurisms, aneurisms, dilation, infection, and device failure. Since classification of this device, the agency has established certain labeling, testing, and manufacturing controls to minimize the potential of the identified risks to health. These controls are discussed in this guidance document. Because the agency believes that the information contained in this guidance document is adequate to address the identified risks to health, the agency is proposing that the ''Document for Special Controls for Vascular Prostheses'' be a special control for the vascular graft prosthesis of less than 6-millimeters diameter (§ 870.3450).

8. ''Document for Special Controls for Annuloplasty Rings''

During the classification of the preamendments devices, the Circulatory System Devices Classification Panel identified as a risk to health associated with the use of the annuloplasty ring, the potentials for: Stenosis, thrombosis, thromboembolism, regurgitation, ring fracture, obstruction, low cardiac output, ring dehiscence, endocarditis, bleeding, blockage, and suture injury. Since classification of this device, the agency has established certain labeling, testing, and manufacturing controls to minimize the potential of the identified risks to health. These controls are discussed in this guidance document. Because the agency believes that the information contained in this

guidance document is adequate to address the identified risks to health, the agency is proposing that the ''Document for Special Controls for Annuloplasty Rings'' be a special control for the annuloplasty ring (§ 870.3800).

9. ''Document for Special Controls for the Cardiopulmonary Bypass Defoamer''

During the classification of the preamendments devices, the Circulatory System Devices Classification Panel identified as risks to health associated with the use of the cardiopulmonary bypass defoamer, the potentials for: Blood damage, gaseous embolism, thromboembolism, blood incompatibility, and inadequate blood flow. Since classification of this device, the agency has established labeling, testing, and manufacturing controls to minimize the potential of the identified risks to health. These controls are discussed in this guidance document. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Document for Special Controls for the Cardiopulmonary Bypass Defoamer'' be a special control for the cardiopulmonary bypass defoamer (§ 870.4230).

10. ''Document for Special Controls for the Cardiopulmonary Bypass Arterial Filter''

During the classification of the preamendments devices, the Circulatory System Devices Classification Panel identified as risks to health associated with the use of the cardiopulmonary bypass arterial filter, the potentials for: Gaseous embolism, thromboembolism, blood incompatibility, and inadequate blood flow. Since classification of this device, the agency has established certain labeling, testing, and manufacturing controls to minimize the potential of the identified risks to health. These controls are discussed in this guidance document. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Document for Special Controls for the Cardiopulmonary Bypass Arterial Filter'' be a special control for the cardiopulmonary bypass arterial line blood filter (§ 870.4260).

11. ''Information for Manufacturers Seeking Marketing Clearance for Blood–Gas Exchangers (Oxygenators) Used in Cardiopulmonary Bypass''

During the classification of the preamendments devices, the Circulatory System Devices Classification Panel identified as risks to health associated with the use of the cardiopulmonary bypass oxygenator, the potentials for: Failure, improper gas transfer function, hemolysis, destruction of platelets and white blood cells, sludging, leaking, and emboli formation. Since classification of this device, the agency has developed a guidance document describing its present conclusions regarding the testing, labeling, and manufacturing controls that would be necessary to ensure the safety and effectiveness of the cardiopulmonary bypass oxygenator. The controls are discussed in this guidance document. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Information for Manufacturers Seeking Marketing Clearance for Blood–Gas Exchangers'' be a special control for the cardiopulmonary bypass oxygenator (§ 870.4350).

12. ''Guidance Document for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads''

During the classification of the preamendments devices, the Circulatory System Devices Classification Panel identified as risks to health associated with the use of the pacemaker lead adaptor, improper pacing, failure to pace, and tissue damage. Since classification of this device, the agency has developed a guidance document describing its present conclusions regarding the research and marketing information which should be submitted to the agency to support 510(k) clearance for pacemaker lead adaptors. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risk to health, the agency is proposing that the ''Guidance Document for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads'' be a special control for the pacemaker lead adaptor (§ 870.3620).

13. ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits''

During the classification of the preamendments devices, the Dental Product Classification Panel identified as risks to health common to the use of certain denture accessories, complications resulting from an alteration of the vertical dimension of a patient's jaw and irritation of oral tissues. Since classification of these devices, the agency has developed a guidance document describing its present conclusions regarding procedures to minimize the risk of such complications. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits'' be a special control for the following four devices: OTC denture cushion or pad (§ 872.3540), OTC denture reliner (§ 872.3560), OTC denture repair kit (§ 872.3570), and partially fabricated denture kit (§ 872.3600).

14. ''Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification''

During the classification of the preamendments devices, the Ear, Nose, and Throat Devices Classification Panel identified as risks to health associated with the use of the tympanostomy tube with semipermeable membrane, the potentials for hearing loss or premature extrusion. Since classification of this device, the agency has developed a guidance document describing its present conclusions regarding the labeling, testing, and manufacturing information which should be submitted to the agency to support 510(k) clearance for tympanostomy tubes. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the document titled ''Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification'' be a special control for the tympanostomy tube with semipermeable membrane (§ 874.3930).

15. ''Guidance for the Content of Premarket Notifications for Intracorporal Lithotripters''

During the classification of the preamendments devices, the Gastroenterology–Urology Devices Classification Panel identified as risks to health associated with the use of the electrohydraulic lithotripter, potential: Infection, tissue damage, failure, breakage, bleeding, pain, renal damage, and the formation of new stones. Since classification of this device, the agency

has developed a guidance document describing its present conclusions regarding the labeling, testing, and manufacturing information which should be submitted to the agency to support 510(k) clearance for lithotripters. Because the agency believes that the information contained in the guidance document, when coupled with the guidance document described below, is adequate to control for the identified risks to health, the agency is proposing that the ''Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters'' be a special control for the electrohydraulic lithotripter (§ 876.4480).

To further minimize the potential risk of infection associated with the reuse of electrohydraulic lithotripters, the agency believes that certain labeling regarding the reuse of the device is appropriate. The agency has developed a guidance document describing its present conclusions regarding the labeling for certain reusable devices. FDA is also proposing that the guidance document entitled ''Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance'' be a special control for the electrohydraulic lithotripter (§ 876.4480).

16. ''Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers, Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems, Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis, and Guidance for Hemodialyzer Reuse Labeling''

During the classification of the preamendments devices, the Gastroenterology–Urology Devices Classification Panel identified as risks to health associated with the use of the high permeability hemodialysis system, potential infection, electrical injury, adverse tissue reaction, pyrogen reaction, hemolysis, electrolyte imbalance, hypovolemic shock, air embolisms, loss of protein, and blood loss. Since classification of this device, the agency has developed four guidance documents describing its present conclusions regarding the labeling, testing, and manufacturing information which should be submitted to the agency to support 510(k) clearance for hemodialysis devices and accessories. Because the agency believes that the information contained in the guidance

documents is adequate to control for the identified risks to health, the agency is proposing that these four guidance documents be applied as special controls for the high permeability hemodialysis system (§ 876.5860).

17. ''Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses''

During the classification of the preamendments devices, the General and Plastic Surgery Devices Classification Panel and the Ear, Nose, and Throat Devices Classification Panel identified as potential risks to health common to the use of the esophageal prosthesis and the tracheal prosthesis, certain complications resulting from migration, obstruction, or placement of the devices, and potential gastric reflux associated with the use of the esophageal prosthesis. Since classification of these devices, the agency has developed a guidance document describing its present conclusions regarding the labeling, biocompatibility testing, mechanical testing, sterilization procedures and labeling, and clinical data controls for esophageal or tracheal prostheses seeking 510(k) clearance. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses'' be a special control for the following two devices: Esophageal prosthesis (§ 878.3610) and tracheal prosthesis (§ 878.3720).

18. ''Guidance for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories)''

During the classification of the preamendments devices, the Obstetrical and Gynecological Devices Classification Panel identified potential complications from use in pregnant women as a risk to health associated with the use of endoscopic electrocautery. Since classification of these devices, the agency has developed a document which provides information for the evaluation of laproscopic and bipolar thermal coagulators. Among the information contained in this document, is a discussion of the agency's present conclusions regarding the labeling, testing, and manufacturing of such devices. Because the agency believes that the information contained in the

document is adequate to control for the identified risk to health, the agency is proposing that the ''Guidance for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories)'' be a special control for the endoscopic electrocautery and accessories (§ 884.4100) and the bipolar endoscopic coagulator-cutter and accessories (§ 884.4150).

19. ''Keratoprosthesis Guidance Document''

During the classification of the preamendments devices, the Ophthalmic Devices Classification Panel identified as risks to health associated with keratoprostheses, potentials for extrusion, infection, adverse tissue reaction, glaucoma, retinal detachment, and development of a retroprosthetic membrane. Since classification of this device, the agency has developed a guidance document describing its present conclusions regarding the labeling, testing, and manufacturing information which should be submitted to the agency to support 510(k) clearance for keratoprosthesis devices. Because the agency believes that the information contained in the guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Keratoprosthesis Guidance Document'' be a special control for the keratoprosthesis (§ 886.3400).

20. ''Aqueous Shunt–510(k) Submission''

During the classification of the preamendments devices, the Ophthalmic Devices Classification Panel identified as risks to health associated with aqueous shunts, the potentials for hypotony, extrusion, infection, adverse tissue reaction, misplacement, migration, and failure to filter. Since classification of these devices, the agency has developed a guidance document describing its present conclusions regarding the labeling, testing, and manufacturing information to be submitted to the agency to support 510(k) clearance for aqueous shunts. Because the agency believes that the information contained in the guidance document is adequate to control for the identified risks to health, the agency is proposing that the ''Aqueous Shunt–510(k) Submission'' be a special control for the eye valve implant (§ 886.3920).

21. ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement, Guidance Document for Testing Non-articulating, Mechanically Locked' Modular Implant Components and Guidance Document for the Preparation of Premarket Notification (510(k) Applications for Orthopedic Devices''

During the classification of the preamendments devices, the Orthopedic and Rehabilitation Devices Classification Panel identified as risks to health common to the use of certain orthopedic implants, the potential for: Pain, loss of joint function, adverse tissue reaction, infection, and device failure. Since classification of these devices, the agency has provided more information about the agency's present conclusions regarding the labeling, testing, and manufacturing information required for 510(k) clearance of orthopedic devices, the agency has also developed the guidance document titled ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices.'' Because the information contained in these guidance documents will help minimize the risks to health, the agency is proposing that these guidances be applied as a special control for the following four devices: Elbow joint metal/polymer constrained cemented prosthesis (§ 888.3150), knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540), shoulder joint metal/polymer nonconstrained cemented prosthesis (§ 888.3650), and shoulder joint metal/polymer semi-constrained cemented prosthesis (§ 888.3660).

*B. Consensus Standards*

FDA has a long history of participating in the development of consensus standards relating to the safety and effectiveness of medical devices. These consensus standards are developed by independent standards organizations based upon discussions among experts from industry, the agency, and other interested parties, and after a series of ballots on draft and final documents. Consensus standards define terminology, describe test methods, and set performance limits for a given product or products. The agency believes that conformity with a consensus standard helps to ensure acceptable quality and performance of the device to which the standard is applied. The

use of standards helps to ensure the safety and effectiveness of the devices to which the consensus standards apply, and it helps to minimize the potential risks to health associated with the use of these devices.

Section 204 of FDAMA amended section 514 of the act (21 U.S.C. 360d) to allow the agency to recognize consensus standards established by international and national standards development organizations for use in certain regulatory decision making concerning devices. On February 25, 1998 (63 FR 9561), FDA issued a notice of availability of a guidance entitled ''Guidance on the Recognition and Use of Consensus Standards'' and also published in that document a list of the consensus standards that FDA was recognizing for use in the premarket review process. FDA will update this list at least annually.

Consensus standards are periodically updated as new information becomes available. When a consensus standard that has been identified as a special control is revised, the agency will publish in the **Federal Register** a proposal to amend the special controls for the relevant devices to include the revised consensus standard.

Accordingly, the agency is proposing that the following consensus standards be adopted as special controls for the devices identified:

1. American Society for Testing and Materials (ASTM) Standards

These standards may be obtained from ASTM Customer Services, 100 Barr Harbor Dr., West Conshohocken, PA 19428 (Telephone 610–832–9585). ASTM also maintains a site on the WWW at the address ''http://www.astm.org''.

a. The following standard is proposed as a special control for the cutaneous oxygen monitor (21 CFR 868.2500) ASTM F984–86: ''Specification for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide.''

b. The following seven standards are proposed as special controls for the elbow joint metal/ polymer constrained cemented prosthesis (§ 888.3150), the knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540), the shoulder joint metal/polymer

nonconstrained cemented prosthesis (§ 888.3650), and the shoulder joint metal/polymer semi-constrained cemented prosthesis (§ 888.3660):

(1) ASTM F75–92 ''Specification for Cast Cobalt–Chromium–Molybdenum Alloy for Surgical Implant Material,''

(2) STM F799–96 ''Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Forgings for Surgical Implants,''

(3) ASTM F1108–97 ''Specification for Ti6Al4V Alloy Castings for Surgical Implants,''

(4) ASTM F648–96 ''Specification for Ultra–High–Molecular–Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(5) ASTM F1537–94 ''Specification for Wrought Cobalt–Chromium–Molybdenum Alloy for Surgical Implants,''

(6) ASTM 1044 ''Test Method for Shear Testing of Porous Metal Coatings,'' and

(7) ASTM 1147 ''Test Method for Tension Testing of Porous Metal Coatings.''

c. The following standards are proposed as special controls for the knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540):

(1) ASTM F370–94 ''Specification for Proximal Femoral Prosthesis,''

(2) ASTM F1672–95 ''Specification for Resurfacing Patellar Prosthesis,'' and

(3) ASTM F1223–96 ''Test Method for Determination of Total Knee Replacement Constraint.''

d. The following standard is proposed as a special control for the elbow joint metal/polymer constrained cemented prosthesis (§ 888.3150) ASTM 981: ''Practice for Assessment of Compatibility of Biomaterials for Surgical Implant with Respect to Effect of Material on Muscle and Bone.''

e. The following standard is proposed as a special control for the shoulder joint metal/polymer nonconstrained cemented prosthesis (§ 888.3650), and the shoulder joint metal/polymer semi-constrained cemented prosthesis (§ 888.3660) ASTM 1378: ''Specification for Shoulder Prosthesis.''

2. American National Standards Institute/American Association for Medical Instrumentation (ANSI/AAMI)

These standards may be obtained from ANSI/AAMI, 11 West 42d St., New York, NY 10036. ANSI also maintains a site on the world wide web at ''http://www.ansi.org''. FDA proposes the following ANSI/AAMI standards as special controls for the identified devices:

a. ANSI/AAMI DF2 ''Cardiac Defibrillator Devices'' as applied to the external transcutaneous cardiac pacemaker (noninvasive) (21 CFR 870.5550);

b. ANSI/AAMI/ISO 11135 ''Medical Devices–Validation and Routine Control of Ethylene Oxide Sterilization'' as applied to the peritoneo-venous shunt (§ 876.5955); and

c. ANSI/AAMI HF–18 ''Electrosurgical Devices'' as applied to the endoscopic electrocautery and accessories (§ 884.4100), the bipolar endoscopic coagulator-cutter and accessories (§ 884.4150), and the electrohydraulic lithotriptor (§ 876.4480).

3. International Standards Organization (ISO).

These standards may be obtained from International Organization for Standardization, Case Postale, Geneva, Switzerland, CH–1121. ISO also maintains a site on the world wide web at ''http://www.iso.org''.

a. FDA proposes the following ISO standards as special controls for the elbow joint metal/polymer constrained cemented prosthesis (§ 888.3150), the knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540), the shoulder joint metal/polymer nonconstrained cemented prosthesis (§ 888.3650), and the shoulder joint metal/polymer semi-constrained cemented prosthesis (§ 888.3660):

(1) ISO 5832 ''Implants for Surgery–Metallic Materials;''

(2) ISO 5833 ''Implants for Surgery–Acrylic Resin Cements;'' and

(3) ISO 5834 ''Implants for Surgery–Ultra High Molecular Weight Polyethylene;''

(4) ISO 9001 ''Quality Systems–Model for Quality Assurance in Design/Development, Production, Installation, and Servicing;'' and

(5) ISO 6018 ''General Requirements for Marketing, Packaging, and Labeling.''

b. The following ISO standard is proposed as a special control for the elbow joint metal/ polymer constrained cemented prosthesis (§ 888.3150): ISO 14630 ''Non-active Surgical Implants–General Requirements.''

c. The following ISO standard is proposed as a special control for the knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (§ 888.3540): ISO 7207 ''Implants for Surgery–Femoral and Tibial Components for Partial and Total Knee Joint Prostheses.''

4. National Committee for Clinical Laboratory Standards (NCCLS)

Copies of these standards may be obtained from NCCLS Executive Offices, 940 West Valley Rd., suite 1400, Wayne, PA 19087 (Telephone 610–688–0100). NCCLS also maintains a site on the WWW at ''http://www.nccls.org''.

a. FDA proposes the following NCCLS standards as special controls for the rubella virus serological reagents (§ 866.3510):

(1) NCCLS I/LA6 ''Evaluation and Performance Criteria for Multiple Component Test Products Intended for the Detection and Quantitation of Rubella IgG Antibody,''

(2) NCCLS D13 ''Agglutination Characteristics, Methodology, Limitations, and Clinical Validation,''

(3) NCCLS I/LA18 ''Specifications for Immunological Testing for Infectious Diseases,''

(4) NCCLS EP5 ''Evaluation of Precision Performance of Clinical Chemistry Devices,'' and

(5) NCCLS EP10 ''Preliminary Evaluation of Quantitative Clinical Laboratory Methods–Second edition, 1993.''

b. FDA proposes the following NCCLS standards as special controls for the indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer (§ 868.1150), the indwelling blood hydrogen ion concentration (pH) analyzer (§ 868.1170), and the indwelling blood oxygen partial pressure ($P_{O2}$) analyzer (§ 868.1200):

(1) NCCLS EP5 ''Evaluation of Precision Performance of Clinical Chemistry Devices,''

(2) NCCLS EP6 ''Evaluation of the Linearity of Quantitive Analytical Methods,''

(3) NCCLS EP7 ''Interference Testing in Clinical Chemistry''($P_{O2}$) analyzer (21 CFR 868.1200),

(4) NCCLS EP9 ''User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples,'' and

(5) NCCLS EP10 ''Preliminary Evaluation of Quantitative Clinical Laboratory Methods–Second edition, 1993.''

5. International Electrotechnical Commission (IEC)

Copies of these standards may be obtained from IEC, AT3, Rue de Varembe, P.O. Box 131, Geneva, Switzerland, ch–1211. IEC also maintains a site on the WWW at ''http://www.iec.ch''.

a. FDA proposes the following IEC standard as special controls for the indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer (§ 868.1150), the indwelling blood hydrogen ion concentration (pH) analyzer (§ 868.1170), the indwelling blood oxygen partial pressure ($P_{O2}$) analyzer (§ 868.1200), the electrohydraulic lithotripter (§ 876.4480), the endoscopic electrocautery and accessories (§ 884.4100), and the bipolar endoscopic coagulator-cutter and accessories (§ 884.4150): IEC 60601 ''Electrical Safety Standard.''

b. FDA also proposes the following IEC standard as a special control for the cutaneous oxygen monitor (§ 868.2500), and the airbrush (§ 872.6080): IEC 601 ''Medical Device Electrical Standard.''

6. Underwriters Laboratory (UL)

These standards may be obtained from Underwriters Laboratories, Inc., 333 Pfingsten Rd., Northbrook, IL 60062 (Telephone 847–272–8800). UL also maintains a site on the WWW at ''http://www.ul.com''.

FDA proposes the following standard as a special control for the cutaneous oxygen monitor (§ 868.2500): UL 2601–1 ''Standard for Safety, Medical Electrical Equipment, Part 1: General Requirements for Safety.''

7. The International Federation of Clinical Chemistry (IFCC)

These standards may be obtained from IFCC through their site on the WWW at ''http:// www.leeds.ac.uk/ifcc''.

FDA proposes the following standard as a special control for the cutaneous oxygen monitor (§ 868.2500): ''IFCC Guidelines for Transcutaneous $P_{O2}$ and $P_{CO2}$ Measurement.''

8. Centers for Disease Control and Prevention (CDC)

CDC has developed standards associated with the detection or prevention of disease. These standards may be obtained from the Center for Disease Control and Prevention, Mail Stop G18, 1600 Clifton Rd., NE., Atlanta, GA 30333.

FDA proposes the following CDC standards as special controls for the rubella virus serological reagents (§ 866.3510):

(1) ''CDC Low Titer Rubella Standard'' as applied to

(2) ''CDC Reference Panel of Well Characterized Rubella Sera.''

9. World Health Organization International (WHO)

WHO has also developed standards associated with the detection or prevention of disease. These standards may be obtained from the World Health Organization International, Laboratory for Biological Standards, Statens Seruminstitut, Center for Prevention and Control of Infectious Diseases and Congenital Disorders, 5. Artillerivej, DK–2300 Copenhagen S, Denmark. FDA proposes the following as a special control for the identified device proposed for reclassification: ''WHO Rubella Standard'' as applied to rubella virus serological reagents (§ 866.3510).

C. Device-specific Labeling

When considering the preamendments devices, the panels identified certain risks to health which would result from the improper use of a device, or use in improper circumstances. The agency believes that general labeling controls such as adequate directions for use, as required by section 502(f) of the act (21 U.S.C. 352(f)), and the labeling requirements for medical devices

in 21 CFR part 801, and for in vitro diagnostic products at 21 CFR 809.10 minimize the potential for most identified risks to health.

However, the agency recognizes that, for certain devices, the general labeling requirements are not sufficiently specific to adequately address and minimize specifically identified risks to health. These risks may be addressed by a more specific labeling regulation (e.g., 21 CFR part 801, subpart H), by guidance, or by issuing specific labeling as a special control. Indeed, several of the FDA guidance documents, which have been identified in this proposal as special controls, contain a section on device labeling. For other devices, no device-specific labeling is addressed in regulations or FDA guidance, although the agency believes that device-specific labeling would be an appropriate special control. Labeling is being proposed as a special control for the following devices:

1. Tinnitus masker (§ 874.3400)

The agency is proposing that the professional labeling of this device contain patient information that describes the risks, benefits, warnings for safe use, and technical specifications of the device in terminology understandable to the average layman. Patient information would also include recommending that the patient seek medical consultation to determine the cause of tinnitus, fitting of the device, and followup care by a hearing health care professional.

2. Tympanostomy tube with semipermeable membrane (§ 874.3930)

The agency is proposing that the labeling for this device describe the risk of clogging, and state that the device is intended for use only in ears that have been evacuated.

3. Endometrial aspirator (§ 884.1060), endometrial brush (§ 884.1100), and endometrial washer (§ 884.1185)

The agency is proposing that the labeling for these devices state that the device is only intended as an adjunctive tool to evaluate the endometrium, and that it is contraindicated in cases of pregnancy, history of uterine perforation, and recent cesarean section. Furthermore, the agency

is proposing that the labeling of the endometrial washer (§ 884.1185) also contain a statement warning that the device should not be attached to wall or any external suction.

4. Endoscopic electrocautery and accessories (§ 884.4100) and bipolar endoscopic coagulator-cutter and accessories (§ 884.4150)

The agency is proposing that the labeling of these devices: Contain an indication for use statement: ''for female tubal sterilization,'' contain instructions for use that recommend destruction of at least 2 cm of the fallopian tube, use of a ''cut'' (or undamped sinusoidal) waveform, and use of minimum power of 25 watts. For devices that have ammeters, the labeling must state that activation of electrode is recommended for 4 to 5 seconds after the visual endpoint is reached or current flow ceases, to achieve complete destruction of tissue.

D. Design and Performance Testing.

The agency has often relied upon consensus standards for the establishment of design specifications for medical devices. For certain devices for which neither consensus standards nor FDA guidances are available to address critical design or performance criteria, the agency believes it is appropriate to identify design specifications and performance testing as a special control. Accordingly, design specifications and performance testing are proposed as special controls for the following devices:

1. External transcutaneous cardiac pacemaker (noninvasive) (§ 870.5550)

The agency is proposing that this device shall not have the capability of delivering pulses in excess of 200 microamperes with a width less than or equal to 50 milliseconds.

2. Tympanostomy tube with semipermeable membrane (§ 874.3930)

The agency is proposing that the membrane material be polytetrafluoroethylene (PTFE) sheeting with no more than a 1-micron pore size and 0.003-inch thickness. Furthermore, the agency is proposing to require functional testing of these devices to verify air passage.

3. Peritoneo-venous shunt (§ 876.5955)

The agency is proposing that these devices provide a specification for backflow that ensures against excessive reflux of blood into the shunt. Furthermore, the agency is proposing that these devices undergo pyrogenicity testing using either the U.S. Pharmacopeia (USP) Rabbit Pyrogen Test or USP Bacterial Endotoxins Test.

4. Endometrial aspirator (§ 884.1060), endometrial brush (§ 884.1100), and endometrial washer (§ 884.1185)

The agency is proposing that these devices be designed such that the sampling part of the device is covered while entering and leaving the vagina. Furthermore, the agency is proposing that the endometrial brush (§ 884.1100) be tested to demonstrate adequate adherence of bristles and brush head, and the endometrial washer (§ 884.1185) undergo testing to demonstrate that maximum intrauterine pressure does not exceed 50 millimeters of mercury.

**VI. Summary of Special Controls**

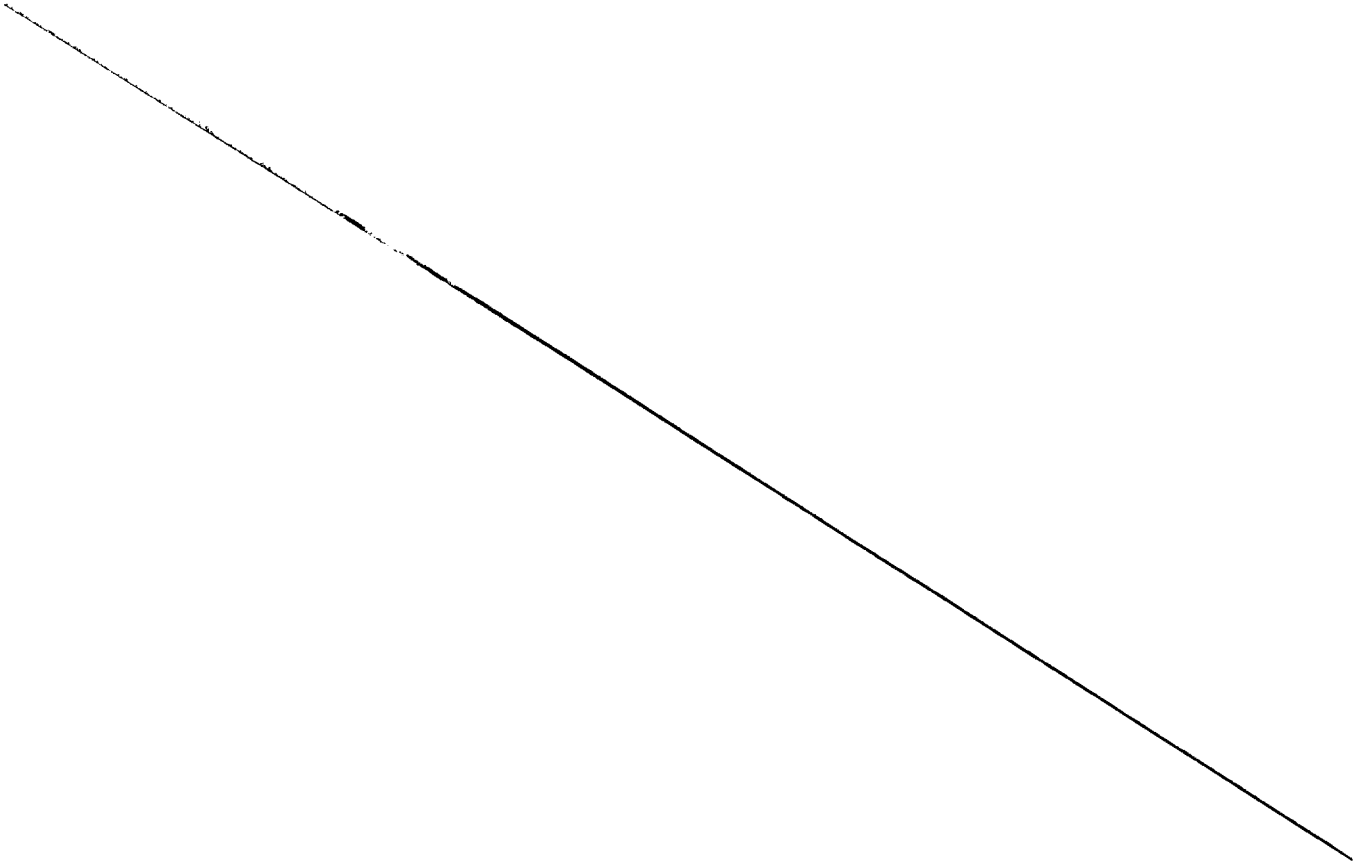

TABLE 2.—SUMMARY OF SPECIAL CONTROLS LISTED BY DEVICE[1]

| CFR Section | Device Name | FDA Sterility Review Guidance | FDA Biocompatibility Guidance | Other FDA Guidance[1] | Labeling | Standards | Design Controls, Performance Testing |
|---|---|---|---|---|---|---|---|
| 864.7250 | Erythropoietin assay | | | 1 | | | |
| 864.7300 | Fibrin monomer paracoagulation test | | | 2 | | | |
| 866.3510 | Rubella virus serological reagents | | | | | NCCLS[2] 1/LA6; 1/LA18; D13; EP5; EP10; CDC[3] Low Titer Rubella Standard; WHO[4] Rubella Standard; CDC Reference Panel of Well Characterized Rubella Sera | |
| 868.1150 | Indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer | X | X | 3, 4, 5 | | NCCLS standards, EP5, EP6, EP7, EP9, EP10, IEC[5] 60601 | |
| 868.1170 | Indwelling blood hydrogen ion concentration (pH) analyzer | X | X | 3, 4, 5 | | NCCLS standards, EP5, EP6, EP7, EP9, EP10, IEC 60601 | |
| 868.1200 | Indwelling blood oxygen partial pressure ($P_{O2}$) analyzer | X | X | 3, 4, 5 | | NCCLS standards, EP5, EP6, EP7, EP9, EP10, IEC 60601 | |
| 868.2500(b) | Cutaneous oxygen monitor | | | | | ASTM[6] F984–86, IEC 601, UL[7] 2601–1, IFCC[8] Guidelines for Transcutaneous $P_{O2}$ and $P_{CO2}$ Measurement | |
| 870.3375 | Cardiovascular intravascular filter | X | X | 6 | | | |
| 870.3450 | Vascular graft prosthesis of less than 6 millimeters diameter | X | X | 7 | | | |
| 870.3620 | Pacemaker lead adaptor | X | X | 8 | | | |
| 870.3800 | Annuloplasty ring | X | X | 9 | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 870.4230 | Cardiopulmonary bypass defoamer | X | X | 10 | | | |
| 870.4260 | Cardiopulmonary bypass arterial line blood filter | X | X | 11 | | | |
| 870.4350 | Cardiopulmonary bypass oxygenator | X | X | 12 | | | |
| 870.5550 | External transcutaneous cardiac pacemaker (noninvasive) | | | | | ANSI/AAMI[9] DF–2 | Shall not have capability of delivering pulses in excess of 200 milliamperes with a width less than or equal to 50 milliseconds |
| 872.3540 | OTC denture cushion or pad | | X | 13 | | | |
| 872.3560 | OTC denture reliner | | X | 13 | | | |
| 872.3570 | OTC denture repair kit | | X | 13 | | | |
| 872.3600 | Partially fabricated denture kit | | X | 13 | | | |
| 872.6080 | Airbrush | | | | | IEC–601 | |
| 874.3400 | Tinnitus masker | | | | Patient labeling re: medical consultation, fitting and follow-up care by a hearing health care professional, risks, benefits, warnings for safe use, and technical specifications | | |
| 874.3930 | Tympanostomy tube with semipermeable membrane | | | 14 | Risk of clogging described,<br>Only for use in ears that have been evacuated | | Functional testing to verify air passage.<br>Membrane material: PTFE[10] sheeting; 1.0 micron pore size; 0.003 inch thickness |
| 876.4480 | Electrohydraulic lithotriptor | X | | 15, 16 | | ANSI/AAMI HF–18<br>IEC 60601 | |
| 876.5860 | High permeability hemodialysis system | | X | 17, 18, 19, 20 | | | |
| 876.5955 | Peritoneo-venous shunt | X | X | | | Sterilization validation per ANSI/AAMI/ISO[11] 11135 | Pyrogeni-city testing per USP Rabbit Pyrogen Test or USP Bacterial Endotoxins Test,<br>Backflow specifications that ensure against excessive reflux of blood into the shunt |
| 878.3610 | Esophageal prosthesis | | | 21 | | | |
| 878.3720 | Tracheal prosthesis | | | 21 | | | |

TABLE 2.—SUMMARY OF SPECIAL CONTROLS LISTED BY DEVICE[1]—Continued

| CFR Section | Device Name | FDA Sterility Review Guidance | FDA Biocompatibility Guidance | Other FDA Guidance[1] | Labeling | Standards | Design Controls, Performance Testing |
|---|---|---|---|---|---|---|---|
| 884.1060 | Endometrial aspirator | X | X | | Only for use as an adjunctive tool to evaluate the endometrium; Contraindications: pregnancy, history of uterine perforation, and recent cesarean section | | Device design to ensure that the sampling part is covered while entering and leaving vagina |
| 884.1100 | Endometrial brush | X | X | | Only for use as an adjunctive tool to evaluate the endometrium; Contraindication: pregnancy, history of uterine perforation, and recent cesarean section | | Device design so that the sampling part is covered within the vagina, Testing to demonstrate adequate adherence of bristles and brush head |
| 884.1185 | Endometrial washer | X | X | | Only for use as an adjunctive tool to evaluate the endometrium; Device should not be attached to wall or any external suction; Contraindications: Pregnancy, history of uterine perforation, and recent cesarean section | | Testing to demonstrate that maximum intrauterine pressure should not exceed 50 millimeters of mercury; Device design so that the sampling part is covered within vagina |
| 884.4100 | Endoscopic electrocautery and accessories | X | | 22 | Indication: female tubal sterilization; Treatment instructions: "destruction of at least 2 cm of tube,"; use of a cut' (or undamped sinusoidal) waveform, and minimum power of 25 watts; For devices with ammeters: activation of electrode for 4 to 5 seconds | IEC 60601 ANSI/ AAMI HF–18 | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 884.4150 | Bipolar endoscopic coagulator-cutter | X | | 22 | Indication: female tubal sterilization; Treatment instructions: "destruction of at least 2 centimeters of tube,"; use of a cut' (or undamped sinusoidal) waveform, and minimum power of 25 watts; For devices with ammeters: activation of electrode for 4 to 5 seconds | | IEC 60601 or ANSI/AAMI HF–18 |
| 886.3400 | Keratoprosthesis | X | X | 23 | | | |
| 886.3920 | Eye valve implant | X | X | 24 | | | |
| 888.3150 | Elbow joint metal/polymer constrained cemented prosthesis | X | X | 25, 26, 27 | | ASTM F75–92, F799–96, F1108–97, F648–96, F1537–94, F981, F1044, F1147; ISO 5832, 5833, 5834, 14630, 10993, 9001, 6018 | |
| 888.3540 | Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis | X | X | 25, 26, 27 | | | ASTM F75–92, F799–96, F1108–97, F648–96, F1537–94, F1044, F1147, F1223–96, F370–94; F1672–95 ISO 5832, 5833, 5834, 6018, 7207, 9001 |
| 888.3650 | Shoulder joint metal/polymer non-constrained cemented prosthesis | X | X | 25, 26, 27 | | | ASTM F75–92, F799–96, F1108–97, F648–96, F1537–94, F1044, F1147, F1378; ISO 5832, 5833, 5834, 6018, 9001 |
| 888.3660 | Shoulder joint metal/polymer semi-constrained cemented prosthesis | X | X | 25, 26, 27 | | ASTM F75–92, F799–96, F1108–97, F648–96, F1537–94, F1044, F1147, F1378; ISO 5832, 5833, 5834, 6018, 9001 | |

[1] The following is a list of guidances FDA has developed to inform manufactures of how the agency evaluates the safety and effectiveness of devices and reaches determination of substantial equivalency:
(1) "Guidance Document for the Submission of Erythropoietin Assay Premarket Notification (510(k)),"
(2) "Guidance Document for the Submission of Fibrin Monomer Paracoagulation Test Premarket Notification (510(k)),"
(3)"Reviewer Guidance for Clinical Studies and Labeling for Indwelling Blood Gas Analyzers,"
(4) "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review,"
(5) "Reviewer Guidance for Format and Content of Premarket Notifications (510(k) Submissions): Labeling, Performance and Environmental Testing for Electronic Devices,"
(6) "Guidance Document for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters,"
(7) "Document for Special Controls for Vascular Prostheses,"
(8) "Guidance Document for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads,"

(9) "Document for Special Controls for the Cardiopulmonary Bypass Defoamer,"
(10) "Document for Special Controls for the Cardiopulmonary Bypass Arterial Filter,"
(11) "Information for Manufacturers Seeking Marketing Clearance for Blood–Gas Exchangers (Oxygenators) Used in Cardiopulmonary Bypass,"
(12) "Document for Special Controls for Annuloplasty Rings,"
(13) "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits,"
(14) "Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification,"
(15) "Guidance for the Content of Premarket Notifications for Intracorporal Lithotripters,"
(16) "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance,"
(17) "Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers,"
(18) "Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems,"
(19) "Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis,"
(20) "Guidance for Hemodialyzer Reuse Labeling,"
(21) "Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses,"
(22) "Guidance for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),"
(23) "Keratoprosthesis Guidance Document,"
(24) "Aqueous Shunt–510(k) Submission,"
(25) "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,"
(26) "Guidance Document for Testing Non-articulating, Mechanically Locked' Modular Implant Components," and
(27) "Guidance Document for the Preparation of Premarket Notification (510(k) Applications for Orthopedic Devices."

[2] National Committee for Clinical Laboratory Standards.
[3] Centers for Disease Control and Prevention.
[4] World Health Organization.
[5] International Electrotechnical Commission.
[6] American National Standards Institute.
[7] Underwriters Laboratories.
[8] International Federation of Clinical Chemistry.
[9] Association for the Advancement of Medical Instrumentation.
[10] Polytetrafluoroethylene.
[11] International Standards Organization.

## VII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages distributive impacts and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of these devices from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act. Moreover, compliance with special controls proposed for these devices will not impose significant new costs on affected manufacturers as most of these devices already comply with the proposed special controls. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this

proposed rule will not impose costs of $100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## X. Submission of Comments and Proposed Effective Dates

Interested persons may, on or before ( *insert date 90 days after date of publication in the* **Federal Register**) submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA proposes that any final regulation that may issue based on this proposal becomes effective 30 days after its date of publication in the **Federal Register**.

## List of Subjects

*21 CFR Part 864*

Blood, Medical devices, Packaging and containers.

*21 CFR Part 866*

Biologics, Laboratories, Medical devices.

*21 CFR Parts 868, 870, 872, 874, 876, 878, 884, and 888*

Medical devices.

*21 CFR Part 886*

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888 be amended as follows:

## PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 864.7250 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

### § 864.7250 Erythropoietin assay.

* * * * *

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance Document for Submission of Erythropoietin Assay Premarket Notification (510(k)).''

3. Section 864.7300 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

### § 864.7300 Fibrin monomer paracoagulation test.

* * * * *

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance Document for Submission of Fibrin Monomer Paracoagulation Test Premarket Notification (510(k)).''

## PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

4. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

5. Section 866.3510 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 866.3510 Rubella virus serological reagents.**

* * * * *

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(b) *Classification.* Class II. The special controls for this device are:

(1) National Committee for Clinical Laboratory Standards':

(i) I/LA6 ''Evaluation and Performance Criteria for Multiple Component Test Products Intended for the Detection and Quantitation of Rubella IgG Antibody,''

(ii) 1/LA18 ''Specifications for Immunological Testing for Infectious Diseases,''

(iii) D13 ''Agglutination Characteristics, Methodology, Limitations, and Clinical Validation,''

(iv) EP5 ''Evaluation of Precision Performance of Clinical Chemistry Devices,'' and

(v) EP10 ''Evaluation of the Linearity of Quantitive Analytical Methods,''

(2) Centers for Disease Control's:

(i) Low Titer Rubella Standard,

(ii) Reference Panel of Well Characterized Rubella Sera, and

(3) World Health Organization's International Rubella Standard.

## PART 868—ANESTHESIOLOGY DEVICES

6. The authority citation for 21 CFR part 868 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

7. Section 868.1150 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 868.1150 Indwelling blood carbon dioxide partial pressure ($P_{CO2}$) analyzer.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(ii) ''Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review,''

(iii) ''Reviewer Guidance for Clinical Studies for Indwelling Blood Gas Analyzers,'' and

(iv) ''Reviewer Guidance for Format and Content of Premarket Notifications (510(k) Submissions), Labeling, Performance and Environmental Testing for Electronic Devices,''

(3) National Committee for Clinical Laboratory Standards':

(i) EP5 ''Evaluation of Precision Performance of Clinical Chemistry Devices,''

(ii) EP6 ''Evaluation of the Linearity of Quantitive Analytical Methods,''

(iii) EP7 ''Interference Testing in Clinical Chemistry,''

(iv) EP9 ''User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples,'' and

(v) EP10 ''Preliminary Evaluation of Quantitative Clinical Laboratory Methods—Second edition, 1993,'' and

(4) International Electrotechnical Commission's 60601 ''Electrical Safety Standard.''

8. Section 868.1170 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

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(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(ii) ''FDA Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review,''

(iii) ''Reviewer Guidance for Clinical Studies for Indwelling Blood Gas Analyzers,'' and

(iv) ''Reviewer Guidance for Format and Content of Premarket Notifications (510(k) Submissions), Labeling, Performance and Environmental Testing for Electronic Devices,''

(3) National Committee for Clinical Laboratory Standards':

(i) EP5 ''Evaluation of Precision Performance of Clinical Chemistry Devices,''

(ii) EP6 ''Evaluation of the Linearity of Quantitive Analytical Methods,''

(iii) EP7 ''Interference Testing in Clinical Chemistry,''

(iv) EP9 ''User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples,'' and

(v) EP10 ''Preliminary Evaluation of Quantitative Clinical Laboratory Methods—Second edition, 1993,'' and

(4) International Electrotechnical Commission's 60601 ''Electrical Safety Standard.''

9. Section 868.1200 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 868.1200 Indwelling blood oxygen partial pressure ($P_{O2}$) analyzer.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k),''

(ii) ''Reviewer Guidance for Clinical Studies for Indwelling Blood Gas Analyzers,''

(iii) ''Reviewer Guidance for Format and Content of Premarket Notifications (510(k) Submissions), Labeling, Performance and Environmental Testing for Electronic Devices,'' and

(iv) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–10,''

(2) National Committee for Clinical Laboratory Standards':

(i) EP5 ''Evaluation of Precision Performance of Clinical Chemistry Devices,''

(ii) EP6 ''Evaluation of the Linearity of Quantitive Analytical Methods,''

(iii) EP7 ''Interference Testing in Clinical Chemistry,''

(iv) EP9 ''User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples,'' and

(v) EP10 ''Preliminary Evaluation of Quantitative Clinical Laboratory Methods—Second edition, 1993,''

(3) International Electrotechnical Commission's 60601 ''Electrical Safety Standard,'' and

(4) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing.''

10. Section 868.2500 is amended by revising paragraph (b)(2) and by removing paragraph (c) to read as follows:

**§ 868.2500 Cutaneous oxygen monitor.**

* * * * *

(b) * * *

(2) *Classification.* Class II. The special controls for this device are:

(i) American Society for Testing and Materials' F984–86 ''Specification for Cutaneous Gas Monitoring Devices for Oxygen and Carbon Dioxide,''

(ii) International Electrotechnical Commission's IEC 601 ''Medical Device Electrical Standard,''

(iii) Underwriters Laboratory's ''Medical Electrical Equipment (UL 2601–1),'' and

(iv) The International Federation of Clinical Chemistry's ''Guidelines for Transcutaneous $P_{O2}$ and $P_{CO2}$ Measurement.''

## PART 870—CARDIOVASCULAR DEVICES

11. The authority citation for 21 CFR part 870 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

12. Section 870.3375 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.3375 Cardiovascular intravascular filter.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–10,'' and

(ii) ''Guidance Document for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters.''

13. Section 870.3450 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.3450 Vascular graft prosthesis of less than 6 millimeters diameter.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–10,'' and

(ii) ''Document on Special Controls for Vascular Prostheses.''

14. Section 870.3620 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.3620 Pacemaker lead adaptor.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,'' and

(ii) ''Guidance Document for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads.''

15. Section 870.3800 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.3800 Annuloplasty rings.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,'' and

(ii) ''Document for Special Controls for Annuloplasty Rings,'' and

(2) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing.''

16. Section 870.4230 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.4230 Cardiopulmonary bypass defoamer.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Bluebook Guidance for Sterility, K90–1,''

(ii) ''Document for Special Controls for Cardiopulmonary Bypass Defoamer,'' and

(2) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing.''

17. Section 870.4260 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.4260 Cardiopulmonary bypass arterial line blood filter.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Bluebook Guidance for Sterility, K90–1,'' and

(ii) ''Document for Special Controls for Cardiopulmonary Bypass Arterial Filters,'' and

(2) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing.''

18. Section 870.4350 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.4350 Cardiopulmonary bypass oxygenator.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,'' and

(ii) ''Information for Manufacturers Seeking Marketing Clearance for Blood Gas Exchangers (Oxygenators) Used in Cardiopulmonary Bypass.''

19. Section 870.5550 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) ''American National Standards Institute/American Association for Medical Instrumentation's DF–2,'' and

(2) The device shall not have capability of delivering pulses in excess of 200 milliamperes with a width less than or equal to 50 milliseconds.

## PART 872—DENTAL DEVICES

20. The authority citation for 21 CFR part 872 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

21. Section 872.3540 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 872.3540 OTC denture cushion or pad.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.''

22. Section 872.3560 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 872.3560 OTC denture reliner.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's ''OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits.''

23. Section 872.3570 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 872.3570 OTC denture repair kit.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's ''OTC Denture Reliners, Repair Kits, Partially Fabricated Denture Kits.''

24. Section 872.3600 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 872.3600 Partially fabricated denture kit.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's ''OTC Denture Reliners, Repair Kits, Partially Fabricated Denture Kits.''

25. Section 872.6080 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 872.6080 Airbrush.**

* * * * *

(b) *Classification.* Class II. The special control for this device is International Electrotechnical Commission's IEC–601 ''Medical Device Electrical Standard.''

## PART 874—EAR, NOSE, AND THROAT DEVICES

26. The authority citation for 21 CFR part 874 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

27. Section 874.3400 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 874.3400 Tinnitus masker.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) Patient labeling to include information about:

(i) Risks,

(ii) Benefits,

(iii) Warnings for safe use, and

(iv) Technical specifications, and

(2) Medical consultation for:

(i) Determination of the cause of tinnitus,

(ii) Fitting of the device, and

(iii) Followup care by a hearing health care professional.

28. Section 874.3930 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 874.3930 Tympanostomy tube with semipermeable membrane.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's ''Tympanostomy Tubes, Submission Guidance for a 510(k),''

(2) Functional testing to verify air passage,

(3) Use of polytetrafluoroethylene sheeting with 1.0 micron pore size and 0.003 inch thickness as membrane material, and

(4) Labeling to:

(i) Describe risk of clogging, and

(ii) State that device is only for use in ears that have been evacuated.

## PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

29. The authority citation for 21 CFR part 876 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

30. Section 876.4480 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows: Kent Giles OFR 3-11-99

**§ 876.4480 Electrohydraulic lithotriptor.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(ii) ''Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters,'' and

(iii) ''Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance,''

(2) American National Standards Institute/American Association for Medical Instrumentation's HF–18 ''Electrosurgical Devices,'' and

(3) International Electrotechnical Commission's IEC 60601 ''Electrical Safety Standard.''

31. Section 876.5860 is amended by revising paragraphs (a) and (b) and by removing paragraph (c) to read as follows:

**§ 876.5860 High permeability hemodialysis system.**

(a) *Identification.* A high permeability hemodialysis system is a device intended for use as an artificial kidney system for the treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, and hemoconcentration. Using a hemodialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional hemodialysis system described in § 876.5820, the high permeability hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices:

(1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient ($K_{uf}$) greater than 12 milliliters per hour per conventional millimeter of mercury, and is used with either an automated ultrafiltration controller or another method of ultrafiltration control to prevent fluid imbalance.

(2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition

of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.).

(3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's:

(i) ''Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers,''

(ii) ''Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems,''

(iii) ''Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis,'' and

(iv) ''Guidance for Hemodialyzer Reuse Labeling.''

32. Section 876.5955 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 876.5955 Peritoneo-venous shunt.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(3) ''Pyrogenicity Testing per USP Rabbit Pyrogen Test or USP Bacterial Endotoxins Test,''

(4) American National Standards Institute/American Association for Medical Instrumentation's ANSI/AAMI/ISO 11135 ''Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization,'' and

(5) Specification for backflow that ensures against excessive reflux of blood into the shunt.

## PART 878—GENERAL AND PLASTIC SURGERY DEVICES

33. The authority citation for 21 CFR part 878 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

### § 878.3610 [Amended]

34. Section 878.3610 is amended by revising paragraphs (a) and (b) and by removing paragraph (c) to read as follows:

### § 878.3610 Esophageal prosthesis.

(a) *Identification.* An esophageal prosthesis is a rigid, flexible, or expandable tubular device constructed of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses.''

35. Section 878.3720 is amended by revising paragraphs (a) and (b) and by removing paragraph (c) to read as follows:

### § 878.3720 Tracheal prosthesis.

(a) *Identification.* The tracheal prosthesis is a rigid, flexible, or expandable tubular device constructed of a silicone, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree. It may be unbranched or

contain one or two branches. The metal tracheal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses.''

## PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

36. The authority citation for 21 CFR part 884 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

37. Section 884.1060 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

### § 884.1060 Endometrial aspirator.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(3) Device design so that sampling part is covered while entering or leaving vagina, and

(4) Labeling to state that the device is only an adjunctive tool to evaluate the endometrium and to contraindicate use of device in pregnant patients and patients with a history of uterus perforation or recent cesarean section.

38. Section 884.1100 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

### § 884.1100 Endometrial brush.

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(3) Device design so that sampling part is covered while entering or leaving vagina,

(4) Testing to demonstrate adequate adherence of bristles and brush head, and

(5) Labeling to state that the device is only an adjunctive tool to evaluate the endometrium and to contraindicate use of device in pregnant patients and patients with a history of uterus perforation or recent cesarean section.

39. Section 884.1185 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 884.1185 Endometrial washer.**

* * * * *

(b) *Classification*. Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(3) Device design so that sampling part is covered while entering or leaving vagina,

(4) Intrauterine pressure not to exceed 50 conventional millimeters of mercury, and

(5) Labeling to:

(i) Contraindicate use of the device in pregnant patients and patients with a history of uterus perforation or recent cesarean section,

(ii) Warn that the device should not be attached to wall or any other external source of suction, and

(iii) State that the device is only an adjunctive tool to evaluate the endometrium.

40. Section 884.4100 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 884.4100 Endoscopic electrocautery and accessories.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's ''Guidelines for Evaluation of Laproscopic Bipolar and Thermal Coagulators,''

(3) International Electrotechnical Commission's IEC 60601 ''Electrical Safety Standard,''

(4) American National Standards Institute/American Association for Medical Instrumentation's HF–18 ''Electrosurgical Devices,''

(5) Labeling: an indication for female tubal sterilization,

(6) Treatment instructions to:

(i) Destroy at least 2 centimeters of a tube,

(ii) Use a cut or undampened sinusoidal waveform, and

(iii) Use a minimum power of 25 watts, and

(7) Labeling of devices with ammeters to activate the electrode for 4 to 5 seconds after the visual endpoint is reached or current flow ceases for complete destruction of tissue.

41. Section 884.4150 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(2) FDA's ''Guidance for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),''

(3) International Electrotechnical Commission's IEC 60601 ''Electrical Safety Standard,''

(4) American National Standards Institute/American Association for Medical Instrumentation's HF–18 ''Electrosurgical Devices,''

(5) Labeling: An indication for female tubal sterilization,

(6) Treatment instructions to:

(i) Destroy at least 2 centimeters of a tube,

(ii) Use a cut or undampened sinusoidal waveform, and

(iii) Use a minimum power of 25 watts, and

(7) Labeling of devices with ammeters to activate the electrode for 4 to 5 seconds after the visual endpoint is reached or current flow ceases for complete destruction of tissue.

## PART 886—OPHTHALMIC DEVICES

42. The authority citation for 21 CFR part 886 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

43. Section 886.3400 is amended by revising paragraphs (a) and (b) and by removing paragraph (c) to read as follows:

### § 886.3400 Keratoprosthesis.

(a) *Identification.* A keratoprosthesis is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye which is not a reasonable candidate for a corneal transplant.

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,'' and

(ii) ''Keratoprosthesis Guidance Document.''

44. Section 886.3920 is amended by revising the section heading and paragraphs (a) and (b) and by removing paragraph (c) to read as follows:

### § 886.3920 Aqueous shunt.

(a) *Identification.* An aqueous shunt is a one-way, pressure sensitive device intended to be implanted to normalize intraocular pressure. The device is intended to treat neovascular glaucoma or glaucomas where medical and conventional surgical treatment have failed.

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,'' and

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,'' and

(ii) ''Aqueous Shunts—510(k) Submissions.''

## PART 888—ORTHOPEDIC DEVICES

45. The authority citation for 21 CFR part 888 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

46. Section 888.3150 is revised to read as follows:

### § 888.3150 Elbow joint metal/polymer constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. It is made exclusively of alloys, such as cobalt-chromium-molybdenum, or of these alloys and of an ultra-high molecular weight polyethylene bushing. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(i) ISO 5832 ''Implants for Surgery—Metallic Materials,''

(ii) ISO 5833 ''Implants for Surgery—Acrylic Resin Cements,''

(iii) ISO 5834 ''Implants for Surgery—Ultra High Molecular Weight Polyethylene,''

(iv) ISO 14630 ''Non-active Surgical Implants—General Requirements,''

(v) ISO 10993 ''Biocompatibility Test Methods,''

(vi) ISO 9001 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(vii) ISO 6018 ''General Requirements for Marketing, Packaging, and Labeling.''

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(ii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iii) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,'' and

(iv) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,'' and

(3) American Society for Testing and Materials':

(i) F75–92 ''Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Material,''

(ii) F799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iii) F1108–97 ''Specification for Ti6Al4V Alloy Castings for Surgical Implants,''

(iv) F648–96 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(v) F1537–94 ''Specification for Wrought Cobalt-Chromium-Molybdenum Alloy for Surgical Implants,''

(vi) F981 ''Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implant with Respect to Effect of Material on Muscle and Bone,''

(vii) F1044 ''Test Method for Shear Testing of Porous Metal Coatings,'' and

(viii) F1147 ''Test Method for Tension Testing of Porous Metal Coatings.''

47. Section 888.3540 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(i) ISO 5832 ''Implants for Surgery—Metallic Materials,''

(ii) ISO 5833 ''Implants for Surgery—Acrylic Resin Cements,''

(iii) ISO 5834 ''Implants for Surgery—Ultra High Molecular Weight Polyethylene,''

(iv) ISO 9001 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,''

(v) ISO 7207 ''Implants for Surgery—Femoral and Tibial Components for Partial and Total Knee Joint Prostheses,'' and

(vi) ISO 6018 ''General Requirements for Marketing, Packaging, and Labeling.''

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(ii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iii) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices,''

(iv) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,'' and

(3) American Society for Testing and Materials':

(i) F75–92 ''Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Material,''

(ii) F799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iii) F1108–97 ''Ti6Al4V Alloy Castings for Surgical Implants,''

(iv) F648–96 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(v) F1537–94 ''Specification for Wrought Cobalt-Chromium-Molybdenum Alloy for Surgical Implants,''

(vi) F1044 ''Test Method for Shear Testing of Porous Metal Coatings,''

(vii) F1147 ''Test Method for Tension Testing of Porous Metal Coatings,''

(viii) F370–94 ''Specification for Proximal Femoral Prosthesis,'' and

(ix) F1672–95 ''Specification for Resurfacing Patellar Prosthesis.''

48. Section 888.3650 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's:

(i) ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(ii) ISO 5832 ''Implants for Surgery—Metallic Materials,''

(iii) ISO 5833 ''Implants for Surgery—Acrylic Resin Cements,''

(iv) ISO 5834 ''Implants for Surgery—Ultra High Molecular Weight Polyethylene,''

(v) ISO 9001 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(vi) ISO 6018 ''General Requirements for Marketing, Packaging, and Labeling.''

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(ii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iii) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,'' and

(iv) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,''

(3) American Society for Testing and Materials':

(i) F75–92 ''Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Material,''

(ii) F799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iii) F1108–97 ''Ti6Al4V Alloy Castings for Surgical Implants,''

(iv) F648–96 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(v) F1537–94 ''Specification for Wrought Cobalt-Chromium-Molybdenum Alloy for Surgical Implants,''

(vi) F1044 ''Test Method for Shear Testing of Porous Metal Coatings,''

(vii) F1147 ''Test Method for Tension Testing of Porous Metal Coatings,'' and

(viii) F1378 ''Specification for Shoulder Prosthesis.''

49. Section 888.3660 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

**§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.**

* * * * *

(b) *Classification.* Class II. The special controls for this device are:

(1) International Standards Organization's:

(i) ISO 10993 ''Biological Evaluation of Medical Devices Part I: Evaluation and Testing,''

(ii) ISO 5832 ''Implants for Surgery—Metallic Materials,''

(iii) ISO 5833 ''Implants for Surgery—Acrylic Resin Cements,''

(iv) ISO 5834 ''Implants for Surgery—Ultra High Molecular Weight Polyethylene,''

(v) ISO 9001 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(vi) ISO 6018 ''General Requirements for Marketing, Packaging, and Labeling,''

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 11/18/94 K90–1,''

(ii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iii) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,'' and

(iv) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,'' and

(3) American Society for Testing and Materials':

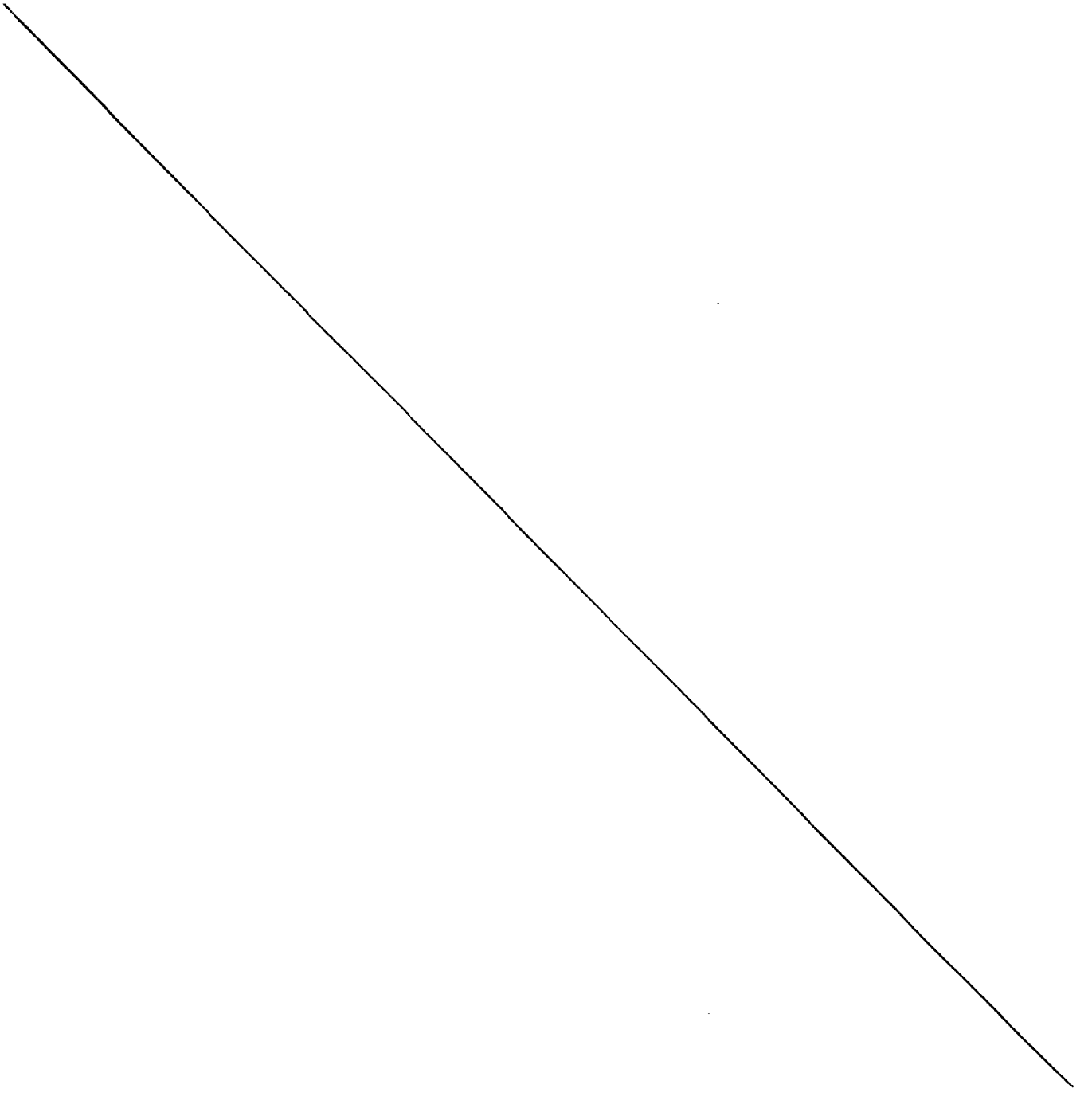
(i) F75–92 ''Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Material,''

(ii) F799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iii) F1108–97 ''Specification for Ti6Al4V Alloy Castings for Surgical Implants,''

(iv) F648–96 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(v) F1537–94 ''Specification for Wrought Cobalt-Chromium-Molybdenum Alloy for Surgical Implants,''



(vi) F1044 ''Test Method for Shear Testing of Porous Metal Coatings,''

(vii) F1147 ''Test Method for Tension Testing of Porous Metal Coatings,'' and

(viii) F1378 ''Standard Specification for Shoulder Prosthesis.''

Dated: March 1, 1999

March 1, 1999

William K. Hubbard
Acting Deputy Commissioner for
Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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